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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,738	12/06/1999	ERIC C. REYNOLDS	040268/0161	3015

7590 02/08/2002
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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 02/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/380,738

Applicant(s)

Reynolds

Examiner

David Lukton

Art Unit

1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Nov 28, 2001

2a) ☐ This action is FINAL.

2b) ☐ This action is non-final.

3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-7, 9-11, 14-26, 30-38, and 41-49 is/are pending in the application

4a) Of the above, claim(s) 1-6, 15-24, and 30-38 is/are withdrawn from consideration

5) ☒ Claim(s) 7, 9-11, 14, 25, 26, and 41-49 is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other:

Pursuant to the directives of paper No. 16 (filed 11/26/01), claims 8, 12, 13, 27, 28, 39, 40 have been cancelled, claims 1, 4, 7, 9-11, 15, 25 amended, and claims 41-49 added. Claims 1-7, 9-11, 14-26, 30-38, 41-49 are pending.

Claims 1-6, 17-24, 30-38 remain withdrawn from consideration. Claims 15-16, previously examined, are now also withdrawn, since they are no longer limited to the elected subject matter. Claim 15 previously was limited to a method of producing a complex, wherein the complex was subgeneric to the complex that was described in claim 7. Now, claim 15 is not limited to any specific complex. For example, claim 16 would encompass a complex which had been obtained by lowering the pH from 9.0 to 6.5, and isolating that material. In addition, claim 15 encompasses the possibility of any number of processes being conducted between steps (iv) and (v), including, for example, removing the phosphopeptide. It is suggested that claim 15 be amended to describe a calcium phosphate complex with sufficient specificity that it is clearly subgeneric to claim 7. If this is done, claims 15-16 will be rejoined.

For purposes of this Office action, claims 7, 9-11, 14, 25, 26, 41-49 are characterized as allowable. The sole issue addressed in this Office action is that of rejoinder of the non-elected claims. Claim 7 is drawn to an **alkaline** calcium phosphate complex in which the calcium phosphate is **alkaline**. Thus, both the complex itself, and the calcium phosphate are alkaline. By contrast, claim 1 does not require the complex itself to be alkaline. In

fact, claim 1 does not necessarily require the amorphous calcium fluoride phosphate to be alkaline. All that claim 1 requires is that somewhere there exists calcium fluoride phosphate which is not necessarily amorphous, but is alkaline. No determination has been made as to what might, or might not constitute new matter. Nevertheless, if rejoinder of the non-elected subject matter is sought, it is suggested that applicants amend claim 1 to mandate that both the complex itself and the amorphous calcium fluoride phosphate are alkaline. If this is done, rejoinder will be considered. However, if claim 1 (and claims subgeneric thereto) are determined to be new matter, the claims will be so rejected. If applicants regard these limitations as new matter, it is suggested that applicants cancel claim 1, and claims subgeneric thereto, or dependent thereon.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle* [1935 C.D. 11, 453 O.G. 213].

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

✱

The following are observations on the claims:

- (a) in claim 11 the first five amino acids are the following:
Gln-Met-Glu-Ala-Gelu-
This contains a typographical error.

(b) In claim 45, there is an error in claim dependence. Presumably dependence on claim 44 is intended.

(c) In claim 47, there is an error in claim dependence. Presumably dependence on claim 46 is intended.

(d) enablement is lacking for claims such as 31, 33 and 35 which assert or imply therapeutic efficacy.

(e) in claim 25, the phrase "such treatment" lacks antecedent basis, and renders the claim non-enabled.

(f) claim 9 should be either cast in independent form, or made dependent on claim 7. As matters currently stand, claim 9 is not subgeneric to claim 41.


(g) claim 9 is indefinite as to the counterion. Can the counterion be a hydronium ion or a proton?

(h) claim 25 is drawn to a method of inhibiting a disease. However, as a semantic matter, one cannot inhibit a state of being, only a process. By way of analogy, one can inhibit the formation of rust, but one cannot inhibit rust *per se*. It is suggested that claim 25 be clearly limited to a method of inhibiting a process. For example, if descriptive support exists for it, applicants could claim the following:

A method of inhibiting demineralization of teeth comprising ...

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


DAVID LUKTON
PATENT EXAMINER
GROUP 1600